

REMARKS

Based upon the foregoing Amendment along with the arguments detailed below, the Applicants respectfully request reconsideration of the outstanding rejection of Claims 1-38. For the reasons detailed herein, the Applicants believe that the pending claims clearly and unequivocally distinguish the prior art references upon which the Examiner has relied and that the claims, as now presented, are all in condition for allowance.

In the Office Action mailed July 2, 2004, the pending claims have been rejected as being anticipated by, or obvious in view of, Dvoretzky, when considered either independently or in combination with Last. Central to the Examiner's argument in rejecting the pending claims is the assertion that Dvoretzky teaches a treatment system which employs a systemic medication that benefits from the application of heat. However, this assertion is erroneous and is directly contrary to the specific teaching found in Dvoretzky.

As clearly and unequivocally detailed in Dvoretzky, heat is applied to a wart in order to inactivate or slow the wart virus which has caused the wart to develop. The heat acts independently and medication is not needed to achieve the desired result. In addition, this reference describes the use of a keratolytic chemical agent, such as salicylic acid or lactic acid. However, as specifically detailed in Column 4, line 60 through Column 5, line 15, the keratolytic chemical agent is employed typically to

reduce the thickness of the epidermis by physically thinning the skin layers. There is no teaching or suggestion in this prior art reference that the keratolytic chemical agent is employed as a systemic medication to be absorbed within the body of the individual, for treating the wart virus. Furthermore, there is no teaching or suggestion in this reference that the keratolytic agent benefits from heat.

As clearly stated in this prior art reference, salicylic acid and/or lactic acid is employed merely to mechanically remove the skin barrier and destroy the superficial skin. These compounds physically remove active skin particles, enabling the skin to become thin, thereby allowing the heat to better and more effectively penetrate the skin and destroy the wart virus found deeper in the tissue. Regardless of whether salicylic acid and/or lactic acid is employed, the heat treatment provided in this prior art reference would be equally effective, since the use of salicylic acid and/or lactic acid is not a requirement for treating the wart virus. Furthermore, these topical medications are not employed for directly treating the wart virus and do not benefit from the application of heat. Consequently, the Examiner's arguments regarding the teaching of this reference are completely incorrect.

As clearly evident from the foregoing explanation, this prior art Dvoretzky reference is devoid of any teaching or suggestion which would lead one of ordinary skill in the art to combine the delivery system taught therein with a systemic medication which is specifically formulated for the treatment of a particular disease or malady and which exhibits improved or enhanced subcutaneous penetration due to the

application of a heat gradient. Since the prior art reference upon which the Examiner has relied (1) contains ***no*** teaching or suggestion regarding the use of any systemic medication which must be absorbed into the bloodstream of an individual in order to achieve the desired efficacy for treating a particular malady, and (2) contains ***no*** teaching or suggestion regarding the selection of a systemic medication which exhibits improved or enhanced penetration from the application of a heat gradient thereto, the Examiner's rejection cannot be sustained. Clearly, the teaching found in the cited prior art reference provides no teaching, suggestion, or motivation which would cause one having ordinary skill in this art to employ the delivery system in combination with a systemic medication, in general, and more particularly, the specific systemic medications defined in Claim 1. As a result, the Applicants believe that Claim 1, as now amended, is patentable over cited prior art references.

Claims 2, 4, 5, 7, 10, 12, 13, and 15-27 are all dependent upon Claim 1 and add novel combinations thereto. For this reason, as well as the reasons detailed above in reference to Claim 1, the Applicants believe that these dependent claims are also in condition for allowance.

In addition, Claims 4, 5, 7, 10, 12, 13, and 15, separately define systemic medications which have been specifically formulated for treating a particular disease or malady and have been found to benefit from the application of a heat gradient for causing the systemic medication to be more quickly and effectively absorbed into the body of the user. In this way, the specific systemic medication is able to be delivered

more effectively and more quickly to the individual seeking the beneficial effects of the medication treatment.

As fully detailed above, the prior art references upon which the Examiner has relied provided no teaching or suggestion regarding the specific systemic medications detailed in these dependent claims and, furthermore, provides no teaching or suggestion regarding the enhanced efficacy attained by applying heat to systemic medication for achieving enhanced delivery and absorption. As a result, the Applicants maintain that these dependent claims are particularly patentable over the cited references and are in condition for allowance.

Claims 28, 29, 31, 33, 35, and 37 are all independent claims which define unique combinations of structural elements forming the treatment system of present invention. In each of these independent claims, the arguments presented above in reference to Claim 1 are equally applicable and are incorporated herein by reference. In addition, in each of these claims, the treatment system is defined as comprising a holding and supporting member which comprises a hollow, continuous, generally cylindrically shaped member which is secured to a desired site where treatment is desired, in peripheral surrounding relationship thereto. Furthermore, the holding and supporting member is further defined as being formed from foamed thermoplastic material configured to provide controlled heat retention and airflow transmission. In addition, the specific foamed thermoplastic material is specifically defined in each of these claims, along with the inclusion of a heat delivery patch or exothermic pad.

Finally, at least one systemic medication which exhibits improved or enhanced penetration from the application of a heat gradient is also defined in each of these claims.

In the outstanding Office Action, these independent claims were all rejected based upon Dvoretzky and Last. In this rejection, the Examiner has erroneously relied upon Dvoretzky for a teaching of a medication component which acts systemically and which exhibits improved or enhanced penetration from the application of a heat gradient. As fully detailed above, Dvoretzky does ***not*** provide the teaching which the Examiner has asserted and, as a result, the Examiner's reliance on this reference is unfounded and unsupportable.

Furthermore, although Last does teach a cylindrically shaped elbow treatment device, this reference fails to provide any teaching or suggestion which would lead one of ordinary skill in the art to construct the holding and supporting member specifically defined in the foregoing claims. In particular, there is ***no*** teaching or suggestion in this reference which would lead one of ordinary skill in the art to construct a holding and supporting member formed from foamed thermoplastic material which is configured to provide controlled heat retention and airflow transmission, as specifically required by these claims. As a result, the Applicants maintain that the combination of references cited by the Examiner is incapable of supporting the Examiner's position and that these independent claims are clearly patentable thereover.

In addition, in Claim 29, the treatment system is defined incorporating all of the limitations detailed above, with the specific systemic medication defined as comprising a chemotherapeutic agent which exhibits improved or enhanced penetration from the application of a heat gradient thereto. For the reasons detailed above, the Applicants maintain that the prior art references upon which the Examiner has relied are clearly incapable of supporting a rejection of the treatment system defined in Claim 29, since no one having ordinary skill in this art would be led to construct the treatment system having all of the components defined in Claim 29, particularly with a chemotherapeutic agent as the systemic medication component. Consequently, the Applicants believe Claim 29 is clearly patentable over the cited references.

In Claim 31, the treatment system is defined incorporating all of the limitations detailed above, with the specific systemic medications defined as comprising a corticosteroid which exhibits improved or enhanced penetration from the application of a heat gradient thereto. For the reasons detailed above, the Applicants maintain that the prior art references upon which the Examiner has relied are incapable of supporting a rejection of the treatment system as defined in Claim 31, since no one having ordinary skill in this art would be lead to construct the treatment system having all of the components defined in Claim 31, particularly with a corticosteroid as a systemic medication components. Consequently, the Applicants maintain that Claim 31 is clearly patentable over the cited references.

In Claim 33, the treatment system is defined incorporating all of the limitations detailed above, with the specific systemic medications defined as comprising an anti-neoplastic which exhibits improved or enhanced penetration from the application of a heat gradient thereto. For the reasons detailed above, the Applicants maintain that the prior art references upon which the Examiner has relied are incapable of supporting a rejection of the treatment system as defined in Claim 33, since no one having ordinary skill in this art would be lead to construct the treatment system having all of the components defined in Claim 33, particularly with an anti-neoplastic as a systemic medication components. Consequently, the Applicants maintain that Claim 33 is clearly patentable over the cited references.

In Claim 35, the treatment system is defined incorporating all of the limitations detailed above, with the specific systemic medications defined as comprising an immunomodulator which exhibits improved or enhanced penetration from the application of a heat gradient thereto. For the reasons detailed above, the Applicants maintain that the prior art references upon which the Examiner has relied are incapable of supporting a rejection of the treatment system as defined in Claim 35, since no one having ordinary skill in this art would be lead to construct the treatment system having all of the components defined in Claim 35, particularly with an immunomodulator as a systemic medication components. Consequently, the Applicants maintain that Claim 35 is clearly patentable over the cited references.

In Claim 37, the treatment system is defined incorporating all of the limitations detailed above, with the specific systemic medications defined as comprising an anti-oxidant which exhibits improved or enhanced penetration from the application of a heat gradient thereto. For the reasons detailed above, the Applicants maintain that the prior art references upon which the Examiner has relied are incapable of supporting a rejection of the treatment system as defined in Claim 37, since no one having ordinary skill in this art would be lead to construct the treatment system having all of the components defined in Claim 37, particularly with an anti-oxidant as a systemic medication components. Consequently, the Applicants maintain that Claim 37 is clearly patentable over the cited references.

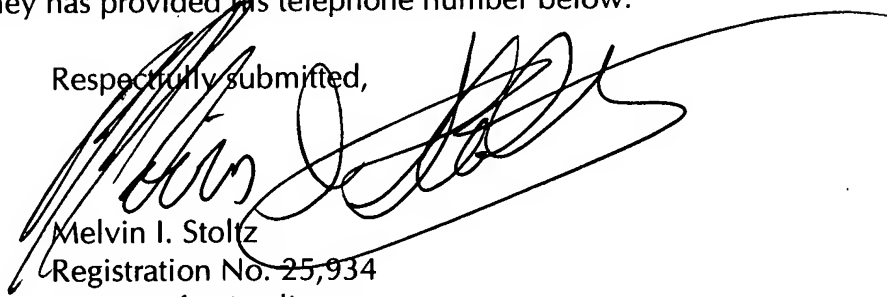
In the foregoing Amendment, the Claims have been amended to obviate the Examiner's objection to the claim phraseology as incorporating non-statutory subject matter. The Applicants believe that the claims as now presented have eliminated this objection.

Based upon the foregoing Amendment, and the arguments presented herein, the Applicants maintain that all of the pending claims, as now amended, overcome the references upon which the Examiner relied and are all in condition for allowance. As a result, an early notice of allowability is earnestly solicited. If any questions remain which may be resolved by a telephone interview, Applicants' undersigned Attorney



would gladly discuss such issues with the Examiner at the Examiner's convenience. For that purpose, Applicants' Attorney has provided his telephone number below.

Respectfully submitted,



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